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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,877	03/07/2002	Ragnhild Frank	10134.200-US	9961
25908	7590	01/14/2004	EXAMINER	
NOVOZYMES NORTH AMERICA, INC.			MILLER, ROSE MARY	
500 FIFTH AVENUE			ART UNIT	
SUITE 1600			PAPER NUMBER	
NEW YORK, NY 10110			2856	

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,877

Applicant(s)

FRANK ET AL. *W*

Examiner

Rose M Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 March 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the granulation or coating device comprising at least one chamber, at least one vibration detecting sensor, amplifying and filtering units, and a computer unit must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-19 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "at least one surface transmitting low frequency vibrations" in claim 1 is used by the claim to indicate the vibrations produced by the particle impacting the surface. The accepted meaning of the term in the prior art is for the surface to "transmit" vibrations into the surrounding environment, such vibrations usually constituting either acoustic or ultrasonic waves that are used in the process. The term is indefinite because the specification does not clearly redefine the term.

A suggestion for correction, in both the specification and the claims, is to remove the reference to "transmitting low frequency vibrations" as it is clear from the rest of the specification (and claims) that the energy measured is a direct result of the impact of the particle(s) on the monitoring surface and/or walls of the reaction chamber and not energy transmitted into the environment surrounding the surface.

Claims 2-19 are rejected as they fail to correct the problem presented by claim 1.

Claims 13-16 are further rejected as the phrase "the granules" lacks a proper antecedent basis. Claim 1, from which claims 13-16 depend, merely recites a granular composition, not specific granules.

Claims 17-19 provide for the use of the method of acoustic emission analysis of claim 1, but, since the claims do not set forth any steps involved in the method/process of preparing granules, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 17-19 are further rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 22 is rejected as being confusing. The claim reads as follows: a "granulation or coating apparatus comprising (a) a granulation or coating device comprising at least one chamber". Why the double recitation of the "granulation or coating"? This leads to the connotation that Applicant is actually claiming two separate apparatuses or devices. A suggestion for correction is to delete the second occurrence and begin the claim with "at least one chamber".

Claim 22 is further rejected as being indefinite as the phrase "optionally amplifying and filtering units and a computer unit" is indefinite as one of ordinary skill in the art could not determine if the amplifying and filtering units or the computer unit are

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actually part of the claimed invention. Therefore the scope of the claim is indefinite and undeterminable at this time.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Belchamber et al. (US 5,040,734)**.

Belchamber et al. discloses an apparatus comprising at least one chamber (1) for processing the product and an arrangement for performing acoustic emission analysis comprising at least one vibration detecting sensor (microphone 3) capable of detecting vibrations in the range of 10 Hz to less than 50 KHz (system operates in range of 50 Hz to 10 KHz, see column 1 lines 54-68) and including amplifying (4) and filtering units (5 and 8) and a computer unit (11).

Belchamber et al. discloses the claimed invention with the exception of the apparatus being monitored comprising a granulation or coating apparatus or device. As this is merely intended use, and the results obtained by the system of **Belchamber et**

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al. are the same, i.e. determining the size of particles or material in the chamber, one of ordinary skill in the art at the time the invention was made would have known to utilize the system of **Belchamber et al.** to monitor a granulation process in addition to the milling process disclosed.

Allowable Subject Matter

7. Claims 1-16 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

8. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record fails to teach and/or suggest a method for acoustic emission analysis of a non-compacted granular composition comprising a biologically active compound comprising colliding the non-compacted granular composition with at least one surface, recording low frequency vibration data in the range of 10 Hz to less than 50 kHz arising from the collision with at least one vibration analyzer and subjecting the recorded low frequency vibration data to computerized data processing.

While it is well known in the art of acoustic emission to monitor the size of particles in a process by measuring the vibrations generated by the impact of the particles on a surface, there is no teaching or suggestion for using such an analysis specifically on a biologically active compound.

Response to Arguments

9. Applicant's arguments with respect to claims 1-19 and 22 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Leach et al. (US 4,024,768) discloses the determination of particle sizes.

Cody et al. (US 5,022,266) discloses the passive acoustics process to monitor a fluidized bed flow.

Hosokawa Micron KK (JP 7-246326) discloses the acoustic monitoring of a granulation apparatus and method.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rose M Miller whose telephone number is 703-305-4923 (571-272-2199 after Jan. 26th). The examiner can normally be reached on Monday - Friday, 7:30 am to 3:30 pm.

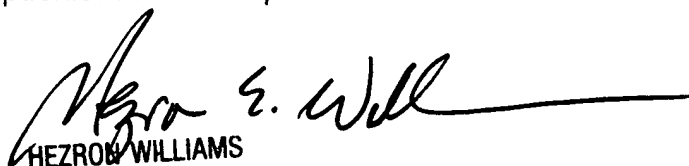
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on 703-305-4705 (571-272-2208 after Jan 26th). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0956.



RMM

9 January 2004


HEZRON WILLIAMS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800